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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/025,195 | 12/19/2001 | David Berd | 1225/1D414US2 | 8483 |

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| EXAMINER | |
|---|---|
| FETTEROLF, BRANDON J | |
| ART UNIT | PAPER NUMBER |
| 1642 | |
| MAIL DATE | DELIVERY MODE |
| 06/23/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/025,195 | BERD, DAVID | |
| | Examiner | Art Unit | |
| | BRANDON J. FETTEROLF | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2,6 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 6, 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to the Amendment*

The Amendment filed on 03/05/2008 in response to the previous Non-Final Office Action (7/23/2007) is acknowledged and has been entered.

Claims 2, 6 and 22 are currently pending and under consideration.

### *Information Disclosure Statement*

The Information Disclosure Statement filed on 1/30/2008 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

**Rejections Withdrawn:**

The rejection of Claims 2, 6 and 22 under 35 U.S.C. 103(a) as being unpatentable over Berd et al. (WO 96/40173, 1996, IDS) in view of Sensi et al. (J. Clin. Invest. 1997; 99: 710-717) is withdrawn in view of Applicants amendments and arguments. In particular, Applicants arguments pertaining to the lack of motivation of changing the administration times in view of Sensi et al..

The rejection of Claims 2, 6 and 22 under 35 U.S.C. 103(a) as being unpatentable over Hoover et al. (Cancer, 1985: 55: 1236-1243, of record) in view of Berd et al. (US 5,290,551, 1994, of record) is withdrawn in view of Applicants amendments and arguments.

**New Rejections Upon Further Consideration:**

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is

either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 6 and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-5, 7-9 and 12 of U.S. Patent No. 6,458,369 in view of Berd et al. (WO 96/40173, 1996, IDS).

US Patent No. 6,458,369 claims a method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to said patient a composition comprising a tumor cell or tumor cell extract with an adjuvant, wherein the tumor cell or tumor cell extract is: (1) conjugated to a hapten; (ii) of the same tumor type as the patients tumor; (iii) not allogeneic to said patient; and (iv) incapable of growing in teh body of the patient after injection; and repeating said administration at weekly intervals, wherein a therapeutically effective amount of cyclophosphamide is administered only prior to the first administration of the composition, wherein the hapten prior to the administration of the composition, and wherein teh composition elicits an anti-tumor response. With regards to the administration, the patent claims that the composition is administered for at least six times. With regards to the tumor cell, the patent claims that the tumor cells include, but are not limited to, colon tumor cells. With regards to the hapten, the patent claims that the haptens include, but are not limited to, dinitrophenyl. With regards to the adjuvant, the patent claims that the adjuvant includes, but is not limited to, Bacillus Calmette-Guerin. With regards to the anti-tumor response, the patent claims that the anti-tumor response is at least tumor necrosis, tumor regression, or tumor infiltration by activated T lymphocytes.

The patent does not explicitly claim that the tumor cells are irradiated. Nor does the patent teach that a booster vaccine was given following the at least six cycles.

Berd et al. teach a method of treating cancer comprising administering cyclophosphamide followed by administering a therapeutically effective amount of a composition comprising a tumor cell or tumor cell extract, wherein the composition is injected ever 4 weeks for a total of eight treatments (page 23, lines 3-9 and lines 23-28). With regards to the cancer cells, the WO document teaches that cancers cells include irradiated tumor cells since it has been found that irradiation of tumor cells prevents them from growing after injection (page 18, lines 24-28). Moreover, the WO document teaches that patients who are considered to be deriving benefit (clinical or immunological) from the therapy regiment, wherein subsequent vaccines may be given without cyclophosphamide (page 30, lines 1-5).

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of the references so as to modify the method claimed in US 6,458,369 so as to irradiate the colon tumor cells and administered a booster vaccine in view of the teachings of Berd et al. One would have been motivated to do so because Berd et al. teach that irradiated tumor cells prevents them from growing within the patient after injection; and further, that patients considered deriving clinical or immunological benefit from therapeutic regmin may receive subsequent vaccines. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by modifying the method claimed in US 6,458,369 so as to irradiate the colon tumor cells and administered a booster vaccine in view of the teachings of Berd et al, one would achieve a method for treating colon cancer.

Therefore, NO claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON J. FETTEROLF whose telephone number is (571)272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf
Primary Examiner
Art Unit 1642

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